

RECEIVED
CENTRAL FAX CENTER

APR 02 2007

REMARKS

Claims 1-3 and 5-12 and 13-17 are pending in the application. Claim 5 has been amended to properly depend from pending Claim 1. Claim 12 has been canceled.

Rejections under 35 USC 102(b)

1. Claims 1-3 and 5-17 stand rejected under 35 USC 102(b) as being anticipated by Niehoff.

It is well settled that in order for a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in prior art. The disclosure requirement under 35 USC 102 presupposes knowledge of one skilled in art of claimed invention, but such presumed knowledge does not grant license to read into prior art reference teachings that are not there. See *Motorola Inc. v. Interdigital Technology Corp.* 43 USPQ2d 1481 (1997 CAFC). It is also well-settled that a 35 USC 102 rejection must rest upon the literal teachings of the reference and that the teachings must disclose every element of the claimed invention in as complete detail as is contained in the claim (See. *Jamesbury Corp v. Litton Industrial Products, Inc.* 225 USPQ, 253, 256 (CAFC 1985); *Kalman v. Kimberly-Clark Corp* 218 USPQ 781, 789 (Fed. Cir. 1983)).

The Office Action alleges that: "The empty syringe is filled by retraction of the plunger while the interior of the syringe communicates with a supply of the contrast fluid via an injection tube connected between the nozzle of the syringe and the supply of media. Then, bubbles are removed from the syringe, and the injection is performed. At the end of the procedure, the syringe plunger typically is forward, as is the plunger drive. "

Applicants' invention of Claims 1, 8 and 11 are directed to a method of preparing for an injection procedure including "advancing the piston to prime the syringe and a tube connected to the syringe."

The novel aspects of Applicants' invention includes that:

[t]he "auto prime" feature allows an injector to automatically prime the fluid path

(i.e., syringe and connecting tubing) before an injection procedure. Preferably, the volume of fluid contained within a connector tubing used with a syringe is pre-programmed into the injector. For example, a 60' low pressure connecting tubing ("LPCT") provided by Medrad, Inc., the Assignee of the present application, for use with its disposable syringes typically holds approximately 2.78 ml of fluid. Alternately, the operator may manually program the fluid volume contained within the connector tube into the injector.

As will become apparent, the auto prime feature may be functionally dependent, in certain respects, on the auto fill feature described above. When a syringe is filled with fluid (i.e., by means of the auto fill feature), the injector automatically compensates for the connector tube by adding its corresponding fluid volume to the fluid volume desired by the operator to be aspirated into the syringe for an injection operation. For example, if the operator desires to fill the syringe with 150ml of fluid for an injection procedure, the auto fill feature will compensate for the connector tube fluid volume by automatically adding 2.78 ml of fluid (e.g., for a 60' LPCT), for a total volume of 152.78 ml aspirated into the syringe. After the syringe is filled with fluid, the auto prime feature would then cause the injector piston to advance the syringe plunger to the extent necessary to expel air from the syringe and connector tube system, preferably without prompting by the operator. Once the auto prime function is conducted, fluid should be present at the patient end of the connector tube (i.e., the end that is connected to the catheter).

As can be appreciated, the auto prime feature may save operator time and reduce the amount of wasted fluid. By automatically compensating for the fluid contained within the connector tube, the operator does not have to vigilantly watch the progression of the fluid from the syringe through the connecting tube in order to stop the advancement of the piston before a significant amount of fluid is discharged from the end of the connector tubing. Also, because some operators of conventional injectors advance the piston quickly to lessen the time required to prime the syringe and tubing system, often a significant amount of fluid will be expelled from the end of the connector tubing before the operator stops the piston's advancement. If a sufficient amount of contrast is expelled, the syringe may have to be re-filled (and the syringe and tubing system subsequently re-primed) to insure that it contains a sufficient amount of fluid for the required injection procedure.

While the auto prime feature is preferably intended for use with empty syringes that have been filled with fluid by an aspiration procedure on the injector (i.e., non-prefilled and non-preloaded syringes), the auto prime feature could also be used with prefilled and preloaded syringes. (Page 59, Para 2 to page 59, para 2).

Niehoff is directed to the injector including a plunger drive controller that

has a locked mode in which motion, initially requested by pressing a manual movement switch, will continue whether or not the operator continues pressing the switch, until the plunger drive reaches its fully-advanced or fully-retracted position. Col 2, line 67 to col. 3, line 4. Niehoff discloses allowing the operator to adjust the rate at which the plunger drive moves or accelerates and essentially moving the syringe based on a "locked mode" or by operator manual control (see col. 5, lines 1- 36). Further, Niehoff discloses storing an offset value representing the length of the extender to apply to the plunger drive jaw. Therefore, Niehoff is directed to controlling the plunger in limited ways, but does not disclose controlling or using the piston to prime the syringe or a tube connected to the syringe.

Accordingly, Niehoff does not disclose any "advancing the piston to prime the syringe and a tube connected to the syringe" of Claims 1 and 11 or "advancing the piston to prime the fluid path" of Claim 8, and thus Applicants' invention is not anticipated by Niehoff.

Claims 2-3, 5-7, 9-10 and 12-15 depend from Claims 1, 8, and 11 respectively, which as discussed herein is believed to be allowable. Thus, Claims 2-3, 5-7, 9-10 and 12-15 are also believed to be allowable. Accordingly, reconsideration of Claims 1-10 is respectfully requested.

2. Claims 1-3 and 5-17 stand rejected under 35 USC 102(b) as being anticipated by Battiato.

As discussed above, Applicants invention includes "advancing the piston to prime the syringe and a tube connected to the syringe" or "advancing the piston to prime the fluid path."

The Office Action alleges that: [Battiato] teaches a method of using an injector (22) with a syringe (38) with a plunger (31) and piston (62) comprising operating a piston in forward and reverse directions either automatically or by hand (with 29) to load, inject and eliminate air from the syringe.

Battiato discloses a "hand-operated motion of the plunger drive ram in either the

forward or reverse direction, allowing the operator to fill the syringe and remove air from the syringe after initial filling. A wide range of movement speeds can be generated with the hand-operated movement control, permitting rapid filling of the syringe. While the power head 22 is in regions 1, 2a or 2b, however, programmed injections are inhibited; thus, the operator cannot initiate injection of a subject according to a pre-programmed injection protocol while the power head 22 is in an upright position." (col. 19, line 61 to col 20, line 3) Battiato does not disclose any priming of the syringe or tube connected to the syringe. Therefore, Battiato does not disclose every element of Applicants' inventions of claims 1, 8 and 11, including "advancing the piston to prime the syringe and a tube connected to the syringe" or "advancing the piston to prime the fluid path. Thus, Claims 1, 8 and 11 are believed to be allowable.

Claims 2-3, 5-7, 9-10 and 12-15 depend from Claims 1, 8, and 11 respectively, which as discussed herein is believed to be allowable. Thus, Claims 2-3, 5-7, 9-10 and 12-15 are also believed to be allowable. Accordingly, reconsideration of Claims 1-10 is respectfully requested.

Double Patenting

Claim 12 has been objected to under 35 CFR 1.75 as being a substantial duplicate of Claim 1. Claim 12 has been cancelled. Thus, the rejection is moot.

RECEIVED
CENTRAL FAX CENTER

APR 02 2007

In view of the above amendments and remarks, Applicants respectfully requests that the Examiner withdraw the rejections of the claims, indicate the allowability of the claims and arrange for an official Notice of Allowance to be issued in due course.

Respectfully submitted,

April 2, 2007

By


Jill Denesvich
Attorney for Applicant(s)
Registration No. 52,810

G:\Legal\Intellectual Property\IP FILES\Patents\CT SBU\FLS II Stellant Syringe Injector and Adapters\00-001.cip.d5
(FLS II - Auto Features)\Amendment 04 02 2007.doc